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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,109	11/19/2001	Helmut Auweter	51964	8082

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KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,109

Applicant(s)

AUWETER ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-16 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-16 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/13/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Supplemental Information Disclosure Statement (IDS) filed 01/22/04, the Amendment and Applicant's Arguments/Remarks, both filed 12/04/03 is acknowledged.

Upon further consideration, the previous Office Action filed 09/23/03 has been *withdrawn*. The following are the new grounds for rejection:

Claims 1-6, 8-16 and 28-33 are pending. Claims 1, 28 and 31 have been amended. Claims 7, 17-27 and 34-40 have been cancelled. Claims 1-6, 8-16 and 28-33 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-16 and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Horn *et al.* (US Pat. No. 4,522,743).

Horn *et al.* disclose preparations of finely divided pulverulent carotenoid and retinoid compositions for use in foodstuffs, animal feed and pharmaceutical applications and processes for making thereof, wherein the process comprises dissolving a carotenoid

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in a volatile, water-miscible, organic solvent (at from 50°C to 200°C), whereby the carotenoid is immediately precipitated in a colloiddally disperse form, from the molecularly disperse solution by mixing the latter with an aqueous solution of a swellable colloid and the resulting dispersion is freed from the solvent and the dispersing medium to yield a finely divided dry powder of carotenoid (see reference column 1, lines 5-20); (col. 2, lines 33-51).

According to Horn *et al.*, the active ingredient concentration in the dispersion obtained after precipitation of the carotenoids can be increased by flocculating the colloiddally disperse system, either by addition of a salt or by bringing it to a suitable pH, and the dispersion can thereby be converted to a form from which a part of the dispersion medium can be separated off by filtering or centrifuging the finely divided carotenoids remaining in the liquid phase. When using a mixture of gelatin and gum arabic as the swellable colloid, the formation – controllable through the pH, of a filterable or sedimentable coacervate can be utilized, particularly advantageously to increase the solids concentration in the dispersion (col. 3, line 65 – col. 4, line 10).

Suitable carotenoids disclosed include, carotene, lycopene, zeaxanthin, citranaxanthin, lutein, canthaxanthin, cryptoxanthin, astaxanthin, β -apo-8'-carotenal, β -apo-8'carotenic acid esters and β -carotene (col. 3, lines 3-15).

Suitable swellable colloids disclosed include, gelatin, starch, dextrin, pectin, gum arabic, casein, caseinate and mixtures of these (col. 3, lines 27-29).

Suitable solvents are, in particular, water-miscible thermally stable volatile solvents containing only carbon, hydrogen and oxygen, (eg. alcohols, ethers, esters, ketones and acetals (col. 3, lines 16-22).

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The Examples at cols. 6-9 demonstrate various processes for producing stable carotenoid dispersion preparations. For instance, Example 2 at column 6, lines 41-56 demonstrates a preparation of a molecularly disperse solution of 5 g of trans- β -carotene in butane-1,2-diol 1-methyl ether, wherein the β -carotene is precipitated in a colloiddally disperse form by mixing the 800 g of an aqueous solution, brought to pH 9.5 with 1N NaOH, of 7.9 g of gelatin and 5.3 g of gum arabic as well as 6 g of dextrose and 3.6 g of dextrin. The pH of the orange-yellow dispersion is then brought to pH 4-4.5 with 1N sulfuric acid and the solid constituent of the dispersion is thereby flocculated. On separating off the liquid phase and repeated washing, a product is obtained which is free from residual solvent and can be converted to a dry powder by spray drying or spray granulation.

Another example of a conventional process is to emulsify the dispersion, which has been freed from solvent, with paraffin oil, cool the mixture, separate the paraffin oil from the encapsulated carotenoid particles, was the resulting carotenoid composition with gasoline and dry the product in a fluidized bed (col. 5, lines 35-40).

Particularly surprising features are that, using the above-mentioned water-miscible solvents at an elevated temperature, the rate of dissolution suffices to give molecularly disperse solutions containing from 0.5 to 10% of the active ingredients (col. 5, lines 41-51).

Horn *et al.* also disclose that on mixing the carotenoid solution, which may additionally contain stabilizers (i.e., ascorbyl palmitate, mono-, di-glycerides, polyglycerol/sorbitol/propylene glycol fatty acid esters, lecithin), with the aqueous solution of the swellable colloids, an extremely finely divided, stable carotenoid

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composition is obtained. It is readily possible to obtain compositions in which the greater part of the active ingredient is present as particles of size about 0.2 μm and without the simultaneous presence of active ingredient particles larger than 1 μm (col. 5, line 52 – col. 6, line 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-16 and 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horn *et al.* (US Pat. No. 4,522,743).

Horn *et al.*, as discussed above, teach preparations of finely divided pulverulent carotenoid and retinoid compositions for use in foodstuffs, animal feed and pharmaceutical applications and processes for making thereof, wherein the process comprises dissolving a carotenoid in a volatile, water-miscible, organic solvent (at from

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50°C to 200°C), whereby the carotenoid is immediately precipitated in a colloiddally disperse form, from the molecularly disperse solution by mixing the latter with an aqueous solution of a swellable colloid and the resulting dispersion is freed from the solvent and the dispersing medium to yield a finely divided dry powder of carotenoid (see reference column 1, lines 5-20); (col. 2, lines 33-51).

According to Horn *et al.*, the active ingredient concentration in the dispersion obtained after precipitation of the carotenoids can be increased by flocculating the colloiddally disperse system, either by addition of a salt or by bringing it to a suitable pH, and the dispersion can thereby be converted to a form from which a part of the dispersion medium can be separated off by filtering or centrifuging the finely divided carotenoids remaining in the liquid phase. When using a mixture of gelatin and gum arabic as the swellable colloid, the formation – controllable through the pH, of a filterable or sedimentable coacervate can be utilized, particularly advantageously to increase the solids concentration in the dispersion (col. 3, line 65 – col. 4, line 10).

Horn *et al.*, teach colloiddally disperse active ingredient suspensions comprising carotenoids, stabilizers, and lipophilic or oily substances, such as fatty acid monoglycerides (see Examples). Horn *et al.* are deficient only in the sense that they do not explicitly teach that the oils are an edible oil liquid or hard fat solid at 20°C. However, it is the position of the Examiner that one of ordinary skill in this art would be fully capable of determining suitable temperatures for either liquid or solid forms through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Moreover, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the

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prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). There is no criticality seen in the use of the instantly claimed temperature. The prior art teaches and recognizes processes for obtaining stable colloidal disperse active ingredient suspensions comprising carotenoids, stabilizers, and lipophilic substances and dry powders obtained therefrom. Hence, the instant invention is rendered *prima facie* obvious over the prior art of record.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-16 and 28-33 have been considered but are moot in view of the new ground(s) of rejection.

Instant claims 1-6, 8-16 and 28-33 have now been rejected under 35 USC §102 & §103 over Horn *et al.* (US Pat. No. 4,522,743). The prior art discloses dry powder carotenoid preparations and processes for producing the same for use in foodstuffs, animal feed and pharmaceutical applications.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,658,377 Craig - 08/1997

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

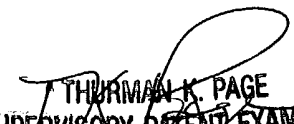
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns *N.S.*

Patent Examiner

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August 13, 2004


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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